

REMARKS

Reconsideration is requested.

The specification has been amended to include sequence identifiers in the description of Figure 5, and after each recitation of KPHMT, as required by the Examiner on page 2 of the Office Action dated February 28, 2005 .

A marked-up and clean replacement specification (318 pages each) are attached which include the Examiner's required amendments. The Amendments of December 22, 2004 have been incorporated in the text of the attached specification. The attached and clean substitute specifications are believed to comply with Rules 121 and 125. The Examiner is requested to advise the undersigned in the event anything further is required in this regard.

The claims have not been amended to include sequence identifiers of KPHMT as the specification exemplifies the structure of KPHMT with the sequences of SEQ ID NOs:7-11 whereas the claims are not limited to any of these sequences. As the inclusion of a sequence identifier in the claims may be construed as a limitation of the recited KPHMT activity or protein, the applicants submit that inclusion of sequence identifiers of any of the exemplified KPHMT sequences in the claims would be inappropriate.

Claim 16 has been amended above to be an independent claim, including the details of claim 5, from which it previously depended. The amended claim is believed to obviate the Rule 75 objection of claim 16. Entry of the amendment and withdrawal of the Rule 75 objection are requested.

The Section 103 rejection of claims 5-8 and 14-16 over "the commercial availability of computers and various software packages such as RASMOL, see the specification the paragraph bridging page 12 and 13, an [sic, as?] admitted prior art, in view of Jones *et al.* [IDS reference : J. Bacteriol. [sic] 1993, Vol. 175, pages 2125-2130]" (see, page 4 of the Office Action dated September 22, 2004 and page 3 of the Office Action dated February 28, 2005) is again traversed. The Section 103 rejection of claim 11 over "the fact that computer homology modeling methods are well known in the prior art, see the specification on page 11, lines 23-25, in view [of] Kurtov et al [IDS reference: Mol. Gene Genet 1999, vol. 262, pages 115-120]" (see, page 3 of the Office Action dated February 28, 2005), is again traversed.

The Examiner is requested to see the applicants remarks of December 22, 2004.

Moreover, with regard to the Examiner's response of February 28, 2005, the applicants submit the following for the Examiner's consideration.

The Examiner, in reaffirming his rejection of the claims based on *In re Gulack* 703 F.2d 1381, 1385 (Fed. Cir. 1983) (hereinafter "Gulack"), is submitted, with due respect, to have focused on part of one paragraph of the judgment of the CAFC.

However, the Examiner appears to ignore the context in which that part of the paragraph was written. The paragraph in full, together with the preceding paragraph (217 USPQ 403-404), read as follows (underlined emphasis added):

"Differences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter.⁸ Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be

read as a whole.⁹ If the board meant to disregard that basic principle of claim interpretation, we must reverse the rejection as a matter of law.

If, instead, the board sought only to construe and apply Miller within the context of a section 103 rejection, we find no error in the board's articulation of the law. Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.¹⁰ Although the printed matter must be considered, in that situation it may not be entitled to patentable weight. This, apparently, was the board's conclusion with respect to Gulack's invention. However, because we find that the digits of Gulack's invention are functionally related to the band, and because Wittcoff fails to disclose or suggest the subject matter recited in the appealed claims, considered as a whole, we reverse."

Footnote 8 of the opinion provides as follows (underlined emphasis added):

A "printed matter rejection" under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art. A printed matter rejection is based on case law antedating the 1952 patent act, employing a point of novelty approach. *In re Sterling*, 70 F.2d 910, 21 USPQ 519 (CCPA 1934). The 1952 act legislatively revised that approach through its requirement that the claim be viewed as a whole in determining obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). The CCPA has considered all of the limitations of the claims including the printed matter limitations, in determining whether the invention would have been obvious. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *In re Cavrich*, 451 F.2d 1091, 172 USPQ 121 (CCPA 1971). In *Royka*, 490 F.2d at 985, 180 USPQ at 583, the CCPA, notably weary of reiterating this point, clearly stated that printed matter may well constitute structural limitations upon which patentability can be predicated.

The present invention is based upon the novel and non-obviousness determination of the three-dimensional structure of the protein KPHMT. The claims

define this structure by reference to a set of X, Y, Z coordinates set out in Table 1. The claims relate to what is essentially a process of drug discovery by utilizing the coordinates to model candidate molecules against the newly discovered KPHMT structure.

The Examiner is understood to assert that because the modelling algorithms by which such a process may be performed are known *per se*, the presently claimed invention must have been obvious.

As emphasized in Footnote 8 of Gulack however, such an approach stands on a “questionable legal and logical footing”. Also as observed by the Gulack panel, it is not permissible to excise the “printed matter” from the claim and then declare the remaining portion unpatentable. The claim “must be read as a whole”.

The presently claimed invention, as a whole, relates to a process in which a model of the newly determined KPHMT structure is utilized to fit to a candidate modulator molecule. The KPHMT structure clearly provides “structural limitations upon which patentability can be predicated”. It would not have been possible, or presently possible, to apply a computer-modeling algorithm in the abstract; nor would applying the algorithm to an unrelated structure be of any use to the skilled person in determining whether or not the modulator would be of potential use in binding to a KPHMT protein.

Accordingly, the particular coordinates of the KPHMT structure are functionally related to any algorithm used for structural modeling, as without the KPHMT structure the algorithm would itself be “non functional”, and with a different protein structure the modeling algorithms would be functionally distinct from the present invention, in that molecular structures would fit differently to them.

The applicants appreciate the Examiner's explanation that the Trilateral report (i.e., "Trilateral Project WM4 Comparative studies in new technologies (biotechnology, business methods, etc.) – Report on Comparative study on protein 3-dimensional (3-D) structure related claims" Vienna, Austria, November 4-8, 2002) is "the stated policy of the United States Patent and Trademark Office." See, page 3 of the Office Action of February 28, 2005. The applicants believe that the Trilateral report is, at best, the interpretation of the law by the Patent Office Solicitor's office. The Trilateral report does not have the effect of law or the Court's interpretation of the law. To at least the extent the Trilateral report is being applied by the present Examiner as a basis to reject the present claims, the applicants submit, with due respect, that it is an incorrect interpretation and application of the law.

As clearly emphasized in Gulack, the PTO

"cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole."

The law, as interpreted by the Courts, such as the CAFC in Gulack is submitted to be controlling on the Patent Office.

For completeness, the applicants submit that in attempting to distinguish the present facts from the finding/holding in Gulack, the Examiner's characterization of the structure of KPHMT as "printed matter" in itself is questionable. A set of atomic coordinates, though printed in Table 1, is a physical representation of the structure of a protein, in the same way that the sequence of a DNA molecule is a paper representation of the chemical structure of a polymer of nucleic acids. Though the Gulak panel of the CAFC do not elaborate on the circumstances where printed matter

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"is not functionally related to the substrate", it is respectfully submitted that this caveat should, like all exceptions, be applied sparingly and with regard to the intention of the patent system to "promote the progress of science and useful arts". A technical process in which the new and useful structure of a protein is provided is clearly subject matter suitable for protection under the Laws of the United States.

The claims are submitted to be patentable over the cited art and withdrawal of the Section 103 rejections is requested, along with a Notice of Allowance.

Respectfully submitted,

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